**Project Summary Report**

**YODA Project Protocol #: 2016-1196**

**From clinical trials to routine care: understanding patient response to biologics in rheumatoid arthritis**

**Status:** Abstract completed and has been prepared for dissemination, publication remains pending

**Abstract prepared by investigators:**


**Objective**
To develop a mapping function that charts American College of Rheumatology (ACR) 20/50/70 and ACRn to Δ Disease Activity Score 28 (DAS28) and the European Alliance of Associations for Rheumatology (EULAR) response, and determine the relationship between the response measures.

**Methods**
Individual patient-level data from the 428 participants randomised to the ATTRACT trial were used. The proportion of participants with ACRn (ACR10-ACR90) response and the change in DAS28 (ΔDAS28) at 30 weeks from baseline were calculated and analysed in participants with complete data. The cut points in ΔDAS28 that provided the equivalent proportion of participants achieving ACR10 to ACR90 at 30 weeks overall and per individual arm were searched for through tabulation. Regression models were conducted and misclassification rates calculated to test the accuracy of the mapping function. The minimum and maximum ACRn achieved per EULAR response category were also determined to establish the correlation of these two response criteria. R version 3.4.3 (2017-11-30) was used for all statistical analyses.

**Results**
53%/27%/12% of all trial participants achieved ACR-ESR 20/50/70 responses, respectively. The mapping function shows that at 30 weeks a 20% improvement in ACR is equivalent to a 27.3% and 27.8% improvement from baseline in DAS28 calculated using ESR and CRP, respectively. 50% improvement in ACR is equivalent to a 45% and 46.2% improvement in DAS28-ESR and DAS28-CRP, respectively. 70% improvement in ACR is equivalent to a lower improvement in the DAS28, at 55.8% for ESR and 59.3% for CRP. Similar results were obtained when analysing the individual arms (Table 1 & Figure 1). Baseline DAS28 for all analysed groups was ≥ 6.0. Moderate or good EULAR responses correspond to 80% and 90% improvement in ACR, respectively, whereas the no response EULAR category showed a maximum improvement in ACR-ESR/CRP of 30%-50%, respectively (Figure 2).

**Conclusions**
This novel mapping function enables the comparison of trials reporting ACR20/50/70 with those reporting ΔDAS28. The results imply nonlinearity in the relationship between ACR20/50/70, ΔDAS28 and EULAR response criteria. Limitations: The mapping is dependent on the population chosen to examine it, which in this analysis comprised trial participants with very active disease.

**Table 1. Mapping between the ACR criteria and change in DAS28**

| | Full cohort (n=428) | Placebo arm (n=88) | IFX arm* (n=86) (3mg/kg every 8 weeks) |
|---|---|---|---|
| | ΔDAS28-ESR (%) | ΔDAS28-ESR (%) | ΔDAS28-ESR (%) |
| **ACR-ESR criteria** | **(Accuracy (%))** | **(Accuracy (%))** | **(Accuracy (%))** |
| 20% improvement | 27.3 (80) | 24 (85) | 29.5 (81) |
| 50% improvement | 45 (85) | 39 (94) | 44 (84) |
| 70% improvement | 55.8 (91) | 44 (91) | 57.9 (86) |
| | ΔDAS28-CRP (%) | ΔDAS28-CRP (%) | ΔDAS28-CRP (%) |
| **ACR-CRP criteria** | **(Accuracy (%))** | **(Accuracy (%))** | **(Accuracy (%))** |
| 20% improvement | 27.8 (83) | 27 (80) | 30 (82) |
| 50% improvement | 46.2 (84) | 44 (92) | 47.5 (84) |
| 70% improvement | 59.3 (93) | 50.8 (92) | 50.8 (84) |

ESR (erythrocyte sedimentation rate); CRP (C-reactive protein concentration).

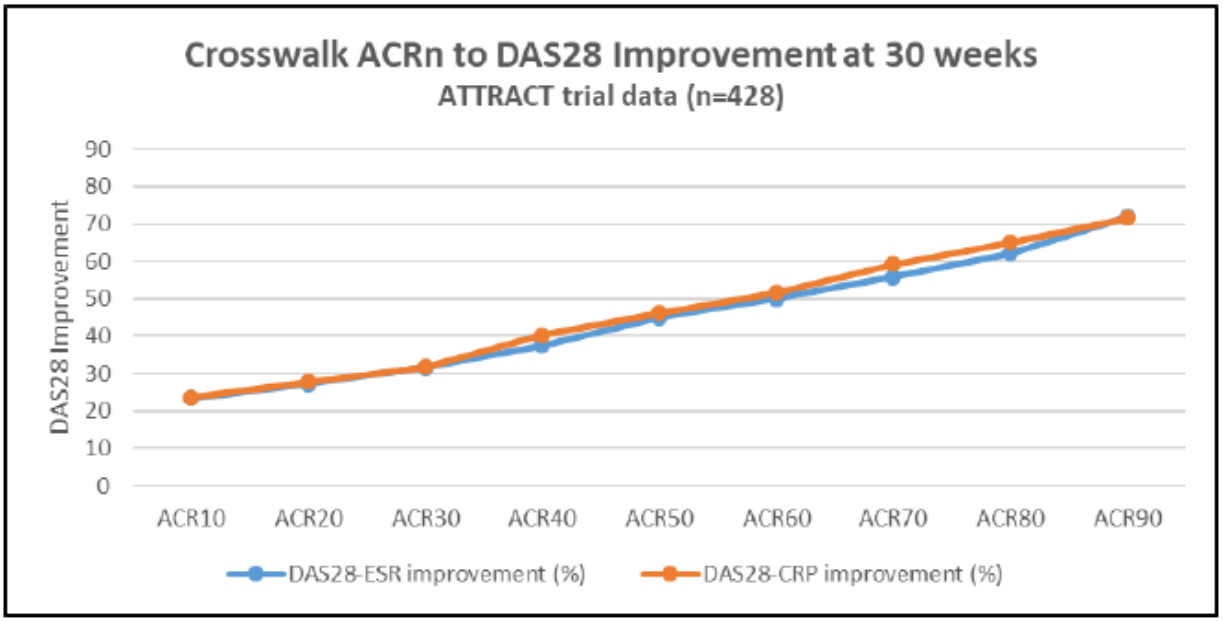


**Figure 1. Mapping between ACRn (ACR10-ACR90) and DAS28 improvement at 30 weeks.**

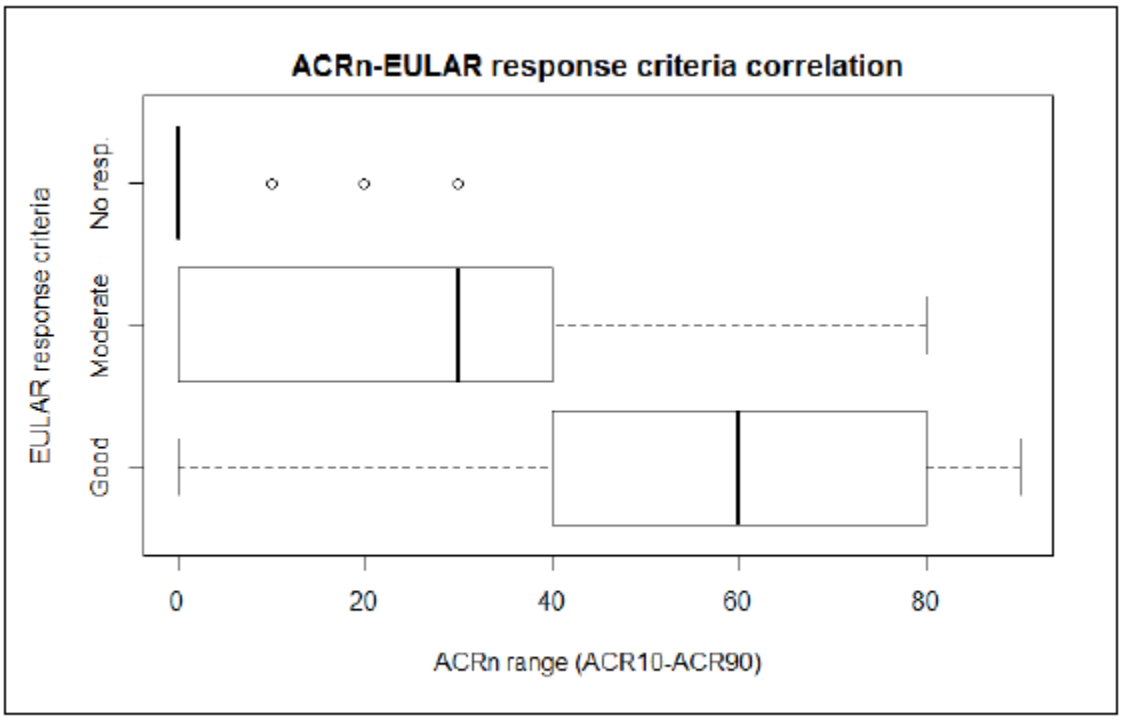


**Figure 2. Correlation of the EULAR and ACR response criteria at 30 weeks.**